

# In the United States Court of Federal Claims

No. 17-79V

Filed: December 3, 2021

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NOT FOR PUBLICATION

**LUKE CAREDIO and JAMIELEE  
CAREDIO, on behalf of their minor  
daughter, D.C.,**

*Petitioners,*

**v.**

**SECRETARY OF HEALTH AND  
HUMAN SERVICES,**

*Respondent.*

*Michael A. Firestone*, Marvin Firestone, MD, JD and Associates, San Mateo, CA, for the petitioners.

*Terrence K. Mangan, Jr.*, Vaccine/Tort Branch, Civil Division, U.S. Department of Justice, Washington, D.C., for the respondent.

## MEMORANDUM OPINION AND ORDER

***HERTLING*, Judge**

The petitioners, Luke and JamieLee Caredio, seek review of a special master's decision denying their claim under the National Vaccine Injury Compensation Program ("Vaccine Program"). On behalf of their minor daughter, D.C., the petitioners allege that D.C. developed *epilepsia partialis continua* ("EPC"), general anxiety disorder, social anxiety disorder, and post-traumatic stress disorder, as a result of an influenza ("flu") vaccination that D.C. received when she was two years old. The special master denied the petitioners' entitlement to compensation.

The petitioners have moved for review of that entitlement decision. They have raised several objections, including the claim that the special master made unsubstantiated credibility

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\* The parties were given until December 17, 2021, to notify the court of any information that should be redacted from this decision for reasons of privilege or confidentiality. Because the parties did not notify the Court of any proposed redactions, the Court hereby releases in full the memorandum opinion and order of December 3, 2021.

findings, reached conclusions unsupported by the evidence, and misapplied the relevant legal standard.

The respondent, the Secretary of Health and Human Services, opposes the petitioners' motion for review.

In applying the deferential standard applicable to motions for review under the Vaccine Program, the Court finds that the special master acted in accordance with the law and did not abuse his discretion or act arbitrarily and capriciously. Accordingly, the petitioners' motion for review is denied.

## **I. BACKGROUND<sup>1</sup>**

### **A. Vaccination and Injury**

In 2014, when D.C. was two years old, she received the flu vaccine during a visit with her primary pediatrician. (ECF 68 at 2.) The petitioners took her to the hospital later the same day because D.C. started shaking while at home. (*Id.*) At the hospital, she had a fever of 103.8 degrees Fahrenheit. (*Id.*) Her diagnosis was fever, likely related to a viral infection. (*Id.* at 3.) The next day the petitioners again took D.C. to the hospital for shaking episodes with a fever. (*Id.*) The doctor could not determine whether D.C. had experienced a febrile seizure or fever-associated chills. (*Id.*)

About three months later, the petitioners sought medical care for D.C. because she had been experiencing eye twitching and an episode in which her head rolled back. (*Id.*) The doctor recommended that the petitioners take D.C. to Valley Children's Hospital for an evaluation of potential seizure activity. (*Id.*) Thus began the multi-year efforts of doctors to identify the source and nature of D.C.'s illness.

Over the next few years, D.C. received medical treatment from Valley Children's Hospital, Stanford University's Lucile Packard Children's Hospital, Memorial Hospital Los Banos, University of California San Francisco ("UCSF") Benioff Children's Hospital, and Boston Children's Hospital. (*Id.* at 3-9.) The doctors performed on D.C. computed tomography scans (commonly referred to as CT scans), electroencephalograms ("EEGs"), and magnetic resonance imaging scans (commonly referred to as MRIs). (*Id.*) The EEG results were consistently abnormal. (*Id.*) At various times during her treatment, D.C. was given steroid medications (prednisone, prednisolone, and methylprednisolone), anti-epileptic medications (Trileptal and Topamax), and intravenous immunoglobulin therapy. (*Id.*)

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<sup>1</sup> The petitioners have not disputed the facts and procedural history as set forth in the special master's entitlement decision. The Court relies on that decision (ECF 68) in providing a summary of the relevant background. The Court omits the special master's internal citations. For a full recitation of the facts, see the special master's decision at *Caredio v. Sec'y of Health & Hum. Servs.*, No. 17-79V, 2021 WL 4100294 (Fed. Cl. Spec. Mstr. July 30, 2021).

D.C.'s condition has been diagnosed as EPC, and EEGs revealed left temporal parietal seizure activity, consistent with focal epilepsy with left posterior hemisphere focus. (*Id.* at 5, 7-9.) Despite years of tests and treatment, however, doctors have been unable to identify the etiology of D.C.'s EPC. (*Id.* at 9.) By the second half of 2016, D.C. also began receiving psychological treatment for behavioral issues associated with her condition and attendant treatments for her seizures. (*Id.* at 8-9.)

## **B. Petition for Compensation**

In January 2017, the petitioners filed their petition for compensation under the Vaccine Program. (ECF 1.) They alleged that the flu vaccination that D.C. received in 2014 was the cause-in-fact of D.C.'s EPC, general anxiety disorder, social anxiety disorder, and post-traumatic stress disorder. (*Id.* at 1.)

After preliminary proceedings, the special master held an entitlement hearing on January 28 and 29, 2021. (ECF 68 at 31.) In addition to medical records, expert reports, and medical literature in the record, the special master heard the testimony of nine witnesses. (*Id.* at 9-31.)

Seven of those witnesses testified for the petitioners. The petitioners presented four fact witnesses: the petitioners, Luke Caredio, D.C.'s father, and JamieLee Caredio, D.C.'s mother; Sharon Caredio, D.C.'s paternal grandmother; and Deborah Townsend, D.C.'s maternal grandmother. (*Id.* at 9-13.) The petitioners also presented two witnesses who had treated D.C.: Keith Van Haren, M.D., a Stanford pediatric neurologist, and Joseph Sullivan, M.D., a neurologist at UCSF. (*Id.* at 13-14, 21-22.) Lawrence Steinman, M.D., Ph.D., a neurologist and immunologist, testified for the petitioners as a non-treating medical expert. (*Id.* at 14-20.)

The respondent put forward two expert witnesses: Christine McCusker, M.D., Ph.D., a pediatric immunologist and microbiologist, and Jenny Linnoila, M.D., Ph.D., a neurologist with a specialty in studying and treating autoimmune diseases. (*Id.* at 22-31.)

As a threshold matter, the special master acknowledged that the "[p]etitioners' testifying treaters largely agreed that D.C. suffered from *some* form of epilepsy, likely EPC . . . ." (ECF 68 at 38 (emphasis in original).) He found "their views to be wholly consistent with the medical record." (*Id.*) He also found that "there is record support, bulwarked by the testimony of treating physicians Drs. Van Haren and Sullivan, that D.C.'s epilepsy/seizures were more likely than not autoimmune in pathogenesis." (*Id.*) The special master found, however, that "[t]he record in this case does *not* . . . support the conclusion that D.C. had or has Rasmussen's syndrome," removing any helpfulness of using an analogy to the autoimmune process relevant to Rasmussen's syndrome in the petitioners' causal theory for D.C.'s EPC. (*Id.* (emphasis in original).)

The special master noted that "Dr. Steinman . . . readily conceded that D.C.'s immediately post-vaccination febrile seizure had *no* relationship to her subsequent development of EPC . . . ." (*Id.* at 39 (emphasis in original).) Dr. Steinman "admitted . . . that his proposed causation theory (that a molecular mimicry-driven cross-reaction instigated by the flu vaccine

produced D.C.'s EPC) *could not occur* in such a short timeframe.” (*Id.* at 39-40 (emphasis in original).) Accordingly, the special master framed the issue in the case as follows: “whether the flu vaccine could precipitate a disease process beginning approximately 10 to 14 days post-vaccination—not the same day as vaccination—and manifesting as eye twitching, but then evolving into outright focal, but afebrile, seizures one to three months later.” (*Id.* at 40.)

Because the petitioners did not assert a claim involving an injury on the Vaccine Injury Table, *see* 42 C.F.R. § 100.3, the special master applied the legal test applicable to Non-Table injuries. To prove causation in a Non-Table case, a petitioner must satisfy by preponderant evidence three elements: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

For the first *Althen* prong, the special master summarized the petitioners’ causal theory, as elaborated by Dr. Steinman:

(a) vaccines impact the immune system, (b) EPC can be an autoimmune condition, (c) vaccines can cause autoimmune diseases, (d) autoimmune processes can occur via the mechanism of molecular mimicry, and (e) homology (necessary to spark an autoimmune cross-reaction based on molecular mimicry) can be demonstrated between components of the flu vaccine and putative neuronal receptors in the brain reflective of the target of an autoimmune cross-reaction sufficient to initiate seizure activity. And [Dr. Steinman] analogized the autoimmune process relevant herein to comparable autoimmune diseases involving intractable seizures, like Rasmussen’s, in which the immune-mediated attack focuses on neuronal brain receptors (although [the] determination that the record does not establish that D.C. had Rasmussen’s limits greatly the value of such analogies).

(ECF 68 at 40.)

The special master found that “[w]hile certain components of this [causal] theory *do* have reputable and reliable scientific/medical support, they do not add up to a causation theory that is more than speculative, as many links necessary for the conclusion that the flu vaccine could cause EPC are missing.” (*Id.* (emphasis in original).) The special master “gave far more weight to Dr. McCusker’s statements and opinions than to those of Dr. Steinman.” (*Id.* at 43.) “Dr. Steinman . . . placed far too much emphasis on molecular mimicry and homology in constructing a causation theory . . . .” (*Id.*)

The special master found the “core deficiency of Dr. Steinman’s opinion” to be the degree to which he relied on sequential homology, which is not enough on its own to establish a preponderant causation theory. (*Id.* at 40-41.) Moreover, Dr. Steinman “ineffectively shield[ed] his theory from challenge either by invoking the limits of science to understand the processes at

issue, admitting outright that his opinion could not be better bulwarked, or acknowledging that he had simply fashioned an opinion that fit the facts of the case.” (*Id.* at 43.)

For the second *Althen* prong, the special master found that “[t]he facts of this case do not preponderantly support the conclusion that D.C.’s receipt of the flu vaccine was responsible for her EPC.” (*Id.* at 44.) He found that “D.C. likely experienced a febrile seizure associated with her receipt of the flu vaccine that same day”; however, “because Dr. Steinman *disavowed* the febrile seizure as having any relationship to D.C.’s later-diagnosed EPC, the vaccine’s causal relationship to a one-time febrile seizure has no bearing on entitlement in this case.” (*Id.* (emphasis in original).) The special master found that D.C.’s medical records do not suggest a relationship between the vaccination and D.C.’s illness, and that Dr. Steinman “was unsuccessful in explaining how a flu vaccine might initiate a neurologic process that would take several months before becoming acute.” (*Id.* at 44-45.)

The special master did not reach the third *Althen* prong. He noted that “although the timeframe prong was substantiated in part with reliable medical and scientific evidence, my reservations about the overall preponderant strength of evidence offered for it makes it difficult for me to conclude that it was satisfied.” (*Id.* at 45.) Although the special master’s findings on the first two *Althen* prongs mooted the need to consider the third prong, he “acknowledge[d] [that] the question was much closer here than in resolving the first two prongs.” (*Id.* at 46.)

The special master concluded that the petitioners had not met their evidentiary burden and, accordingly, dismissed their claim. (*Id.*)

The petitioners thereafter moved for reconsideration and to redact comments that the special master made about Dr. Steinman in two footnotes of the entitlement decision. (ECF 69.) The special master denied both requests. (ECF 70.)

### **C. Motion for Review**

The petitioners have moved for the Court to review the special master’s decision denying compensation. (ECF 71; *see also* ECF 73 (Memorandum of Objections).) The petitioners have raised five objections to the special master’s decision:

- 1) The [special master] made unsubstantiated credibility findings regarding Dr. Steinman;
- 2) The [special master] ignored evidence and unreasonably dismissed Petitioners’ theory of causation which was supported by appropriate medical literature;
- 3) The [special master] made erroneous scientific conclusions that are unsupported by the evidence;
- 4) The [special master] raised Petitioners’ burden of proving *Althen* prong 1 due to his improper credibility findings; and

5) The [special master] raised Petitioners' burden of proving *Althen* prong 2 by requiring definitive and even experimental evidence for Petitioners to prove causation.

(ECF 73 at 1.)

The matter has been fully briefed, and the Court heard oral argument on November 18, 2021.

## II. JURISDICTION AND STANDARD OF REVIEW

The Court of Federal Claims has jurisdiction to review the decisions of special masters under the Vaccine Program. 42 U.S.C. § 300aa-12(e); *see generally* Rules of the Court of Federal Claims ("RCFC") App. B, Title V (providing the rules governing this court's review of a special master's decision). Pursuant to this jurisdiction, the court may "set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law." 42 U.S.C. § 300aa-12(e)(2)(B); *see also* RCFC App. B, Rule 27.

The Federal Circuit has described the standard of review to be applied to the court's review of a decision by a special master as "the most deferential possible." *Munn v. Sec'y of Dep't of Health & Hum. Servs.*, 970 F.2d 863, 870 (Fed. Cir. 1992). This court "owes the[ ] findings and conclusions by the special master great deference—no change may be made absent first a determination that the special master was 'arbitrary and capricious.'" *Id.* The degree of deference depends on which aspect of the special master's judgment is under review. *Id.* at 870 n.10. This court "may set aside the decision of a special master only if the special master's fact findings are arbitrary and capricious, its legal conclusions are not in accordance with law, or its discretionary rulings are an abuse of discretion." *Turner v. Sec'y of Health & Hum. Servs.*, 268 F.3d 1334, 1337 (Fed. Cir. 2001).

## III. DISCUSSION

The petitioners have the burden to prove by preponderant evidence that the flu vaccine caused D.C.'s injuries. *See Althen*, 418 F.3d at 1278. The petitioners do not dispute that they allege Non-Table injuries. Because they allege a Non-Table claim, the petitioners must prove three elements to establish causation: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278. The petitioners also do not dispute that they must satisfy all three *Althen* prongs.

The petitioners have raised five objections to the special master's conclusion that the petitioners failed to meet the three prongs required by *Althen*. (ECF 73 at 1.) Their first objection challenges the special master's credibility determination as to Dr. Steinman. (*Id.*) Their third objection challenges some of the special master's factual and scientific conclusions. (*Id.*) Finally, their second, fourth, and fifth objections challenge the special master's application

of *Althen*, arguing that the special master ignored evidence, allowed the credibility determination to taint his judgment, and improperly raised the petitioners' burden of proof. (*Id.*)

### A. Credibility Determination

The petitioners' first objection is that the special master "made unsubstantiated credibility findings regarding Dr. Steinman." (ECF 73 at 1.) This claim is the crux of much of the petitioners' argument, as they rely on it to urge the Court to find legal error by the special master and therefore not to apply deferential review.<sup>2</sup>

Dr. Steinman was central to the petitioners' claim. As described by the special master, he "was the [petitioners'] primary expert proposing [that] the flu vaccine could cause EPC, as Drs. Sullivan and Van Haren disclaimed offering such an opinion." (ECF 68 at 40.) In evaluating Dr. Steinman's testimony, the special master disparaged his credibility in unusually strong terms.

The petitioners argue that the special master's "demeaning comments in footnotes 8 and 13 [of the entitlement decision] directed at Dr. Steinman revealed an apparent bias and unfavorable opinion of Dr. Steinman's work as an expert witness in the Vaccine Court." (ECF 73 at 7.) In both footnotes cited by the petitioners, the special master referred to and relied on Dr. Steinman's testimony not only in the petitioners' case but also in other vaccine cases.

Specifically, in footnote 8 of his entitlement decision, the special master questioned Dr. Steinman's self-assessment as to how many and the variety of cases of neurological injuries about which Dr. Steinman has testified:

Dr. Steinman testifies frequently in the Program—and has often informed the special masters he appears before that, whatever the injury in question, he has *repeatedly* had occasion to treat or diagnose it. *See, e.g., McGrail v. Sec'y of Health & Hum. Servs.*, No. 17-926V, 2021 WL 1728706, at \*10 (Fed. Cl. Spec. Mstr. Apr. 23, 2021) (estimating he has treated hundreds of patients with transverse myelitis and similar neurological conditions such as multiple sclerosis and neuromyelitis optica); *Salazar v. Sec'y of Health & Hum. Servs.*, No. 15-817V, 2021 WL 319393, at \*9 (Fed. Cl. Spec. Mstr. Jan. 5, 2021) (stating he has cared for hundreds of adults and children with various forms of brachial plexus injuries, peripheral neuropathy, and autoimmune neurologic conditions); *Taylor v. Sec'y of Health & Hum. Servs.*, No. 13-700V, 2018 WL 2050857, at \*7 (Fed. Cl. Mar. 9, 2018) (estimating he has treated over 2,500 patients with multiple sclerosis, Guillain-Barré syndrome ("GBS"), or Acute Demyelinating Encephalomyelitis

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<sup>2</sup> The Court addresses the petitioners' argument regarding the alleged legal error later in evaluating the special master's application of the *Althen* prongs.

(“ADEM”)); *Rolshoven v. Sec’y of Health & Hum. Servs.*, No. 14-439V, 2018 WL 1124737, at \*6 (Fed. Cl. Spec. Mstr. Jan. 11, 2018) (stating he has treated over 1,000 patients with headaches during his 35 year career); *Blackburn v. Sec’y of Health & Hum. Servs.*, No. 10-410V, 2015 WL 425935, at \*7 (Fed. Cl. Jan. 9, 2015) (stating he has treated approximately 400 patients with GBS). But even accepting Dr. Steinman’s overall competence and expertise in neurologic matters, the contention that he has vast deep background exposure to virtually *any* neurologic injury is exceedingly difficult to swallow.

(ECF 68 at 14-15 n.8 (emphasis in original).)

In footnote 13 of the entitlement decision, the special master commented on Dr. Steinman’s perceived role as a medical expert, citing both his testimony in this case and criticism of his testimony in other cases:

I also note that throughout his testimony, Dr. Steinman repeatedly tried to vouch for his own credibility—although doing so backfired. Thus, he purported not to be an advocate for Petitioners herein (Tr. at 163, 166), but instead a neutral professional whose north star was science, emphasizing that he did not always accept cases for claimants when he did not feel he could fairly offer an opinion to support a particular claim (*Id.* at 164). Yet Dr. Steinman admitted his ultimate utility as an expert was measured not by whether he had offered a reliable independent opinion, but rather whether he had crafted an opinion that might help Petitioner succeed. *See, e.g.*, [*id.* at 164] (“when I am seen [at hearing], I can make a theory and support a case”), 166-67 (his goal is to determine “whether I could make any type of theory that would connect the vaccine that petitioner actually received . . . and the injury we’re talking about today”).

In past cases, Dr. Steinman has been criticized for stepping outside his role of medical expert to opine on the legal standards to be applied in Program cases. *See e.g.*, *D.G. v. Sec’y of Health & Hum. Servs.*, No. 11-577V, 2019 WL 2511769, at \*189 (Fed. Cl. Spec. Mstr. May 24, 2019); *Rolshoven v. Sec’y of Health & Hum. Servs.*, No. 14-439V, 2018 WL 1124737, at \*10, 21 (Fed. Cl. Spec. Mstr. Jan. 11, 2018). Although he refrained from doing so in this case, his various asides herein amounted to a different kind of “unforced error” that greatly detracted from his credibility. For he seemed to admit that an expert’s job is to “shill” for the claimant, without regard for the independence and adherence to scientific principles he maintained guided him in deciding whether to offer an opinion in the first place. Dr. Steinman would be well advised in



future cases to stick to the facts, and to explain only why his causation theory is reliable based on his own expertise—not to make comments that suggest he is aware there is less to his opinion than meets the eye.

(*Id.* at 20-21 n.13.)

“Weighing the persuasiveness of particular evidence often requires a finder of fact to assess the reliability of testimony, including expert testimony, and [the Federal Circuit has] made clear that the special masters have that responsibility in Vaccine Act cases.” *Moberly ex rel. Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1325 (Fed. Cir. 2010). Special masters have “broad discretion in determining credibility because [they] saw the witnesses and heard the testimony.” *Bradley v. Sec’y of Dep’t of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). Accordingly, those credibility determinations are “‘virtually unreviewable.’” *Id.* (quoting *Hambsch v. Dep’t of Treasury*, 796 F.2d 430, 436 (Fed. Cir. 1986)).

In the primary analysis rejecting the petitioners’ claim in his entitlement decision, the special master provided reasons independent of those outlined in footnotes 8 and 13. The special master explained in detail his reasons for according more weight to the testimony and opinions of Dr. McCusker, the respondent’s expert, than to the testimony and opinions of Dr. Steinman. (ECF 68 at 43.) Dr. McCusker’s testimony, the special master found, “not only covered overarching weaknesses in Petitioners’ theory, but homed in on the individual elements of Dr. Steinman’s theory, and the views she expressed arose from her specific expertise in pediatric immunology.” (*Id.*) In contrast, the special master found that Dr. Steinman “placed far too much emphasis on molecular mimicry and homology in constructing a causation theory . . . .” (*Id.*) The special master also found that Dr. Steinman “ineffectively shield[ed] his theory from challenge, either by invoking the limits of science to understand the processes at issue, admitting outright that his opinion could not be better bulwarked, or acknowledging that he had simply fashioned an opinion that fit the facts of the case.” (*Id.*) Dr. McCusker, however, “persuasively rebutted the points made in favor of causation.” (*Id.*)

The petitioners’ allegation of bias by the special master against Dr. Steinman is unsupported by the record. Notably, despite the special master’s criticism of Dr. Steinman in the cited footnotes of his entitlement decision, the special master credited Dr. Steinman’s opinion on homology. Specifically, the special master found that Dr. Steinman “*was* able to show amino acid homology between the flu vaccine’s antigenic components and putative antigenic targets in the brain where an autoimmune form of epilepsy *might* occur . . . .” (*Id.* at 41 (emphasis in original).) The special master also acknowledged that “molecular mimicry is unquestionably a reliable scientific theory for how autoimmune diseases can pathologically progress.” (*Id.*) The special master noted that “[o]ther special masters have observed Dr. Steinman’s tendency when acting as a Program expert to ‘shoehorn molecular mimicry into every causation in fact case’ in which he testifies.” (*Id.* at 43 (quoting *D.G. v. Sec’y of Health & Hum. Servs.*, No. 11-577V, 2019 WL 2511769, at \*189 (Fed. Cl. Spec. Mstr. May 24, 2019)).) “That tendency,” the special master found, “was fully on display here, undermining [Dr. Steinman’s] overall credibility.” (*Id.*)

Because “[h]omology does not inexorably lead to disease,” the special master required “more” in order “to establish that a vaccine could prompt harm arising from a potential autoimmune cross-reaction that would occur due to homology . . . .” (*Id.* at 41.) The special master found that the “more” needed to show causation to support the petitioners’ claim was missing. (*Id.* at 41-42.) Ultimately, the special master concluded that “Dr. Steinman’s causation theory over-relied on demonstrating sequence homology between components of the flu vaccine and certain neuronal receptors where focal seizures might occur, but without also proposing additional reliable evidence necessary to find that the flu vaccine could be associated with autoimmune epilepsy/EPC.” (*Id.* at 44.) Therefore, even if the special master’s footnoted comments about Dr. Steinman were improper, those comments were not determinative of the outcome.

In the special master’s decision denying the petitioners’ motion for reconsideration, the special master explained that his footnoted comments about Dr. Steinman were not consequential to the entitlement decision: “Before issuing the [entitlement decision], I read all of [Dr. Steinman’s] reports, listened carefully to him testify, re-read the transcript of that testimony several times, read all literature he offered, and carefully considered his opinion. *These things* were the foundation for my determination – not the soft criticisms set forth in [footnotes 8 and 13].” (ECF 70 at 4 (emphasis in original).) The special master further explained that his “rejection of molecular mimicry in this case as reliably explaining how the flu vaccine could cause D.C.’s seizures was not a blanket dismissal of the theory’s reliability as a general matter, or motivated solely by [the special master’s] view (tempered by experience with Dr. Steinman) that he invokes molecular mimicry too often when testifying.” (*Id.* at 5.) The special master concluded that the result would not have been different if a different expert had offered the same opinion; “Dr. Steinman did not reliably demonstrate that the flu vaccine could have caused D.C.’s EPC . . . .” (*Id.*)

The explanation provided by the special master in his decision denying the motion for reconsideration is consistent with his original explanation for denying compensation in his entitlement decision, and the petitioners have asserted no basis and pointed to no evidence in the record, aside from the two footnotes, to support a finding that the special master was biased or lacked the integrity to address the issue honestly on a motion for reconsideration.

The petitioners also argue that the special master’s footnoted comments about Dr. Steinman constituted unfair surprise, leaving them no opportunity to respond, in violation of the petitioners’ due process rights. The flaw in this argument lies in the fact that the petitioners’ counsel himself raised on direct examination the topic of Dr. Steinman’s role as an expert witness in the Vaccine Program. Petitioners’ counsel asked Dr. Steinman: “And how do you perceive your role in this matter, or any other vaccine matter?” (ECF 66, Tr. at 165.) Dr. Steinman answered by mentioning criticism for his testimony in other cases:

Well, I’d say just about everything I do, I’m constantly learning. So it’s probably about eight years ago, I was admonished for being too zealous for the Petitioner when I agreed. So I would say that since

that admonition from a special master in a decision, I take criticism, and try to improve if I think I should improve.

So now I really, I'm going to tell you the high points and low points even of my own theory.

(*Id.* at 165-66.)

The petitioners' counsel opened this line of inquiry presumably because by the time of the entitlement hearing, the respondent had already put Dr. Steinman's potential advocacy at issue, as evidenced by the petitioners' counsel's next question: "Because the Respondent has argued in this case that you are an advocate and, you know, do you consider yourself to be an advocate?" (*Id.* at 166.) Dr. Steinman then was given the opportunity to respond to the accusation in his answer:

Well, I read the -- what you're talking about, of course, and no, I don't consider myself an advocate, I consider myself a medical scientist with a special field of knowledge that can educate the Court and help them deliberate. That's about what I would say.

Of course, as one gets into this kind of combat in the courtroom, I have to remind myself, just remind yourself, Dr. Steinman, that you're an expert, you're not on the side of one or the other. So I try to tell myself that, but sometimes it becomes inevitable or, you know, we're all competitive. I'll speak for myself, I'm a competitive guy.

(*Id.*) This line of questioning shows that the petitioners had the opportunity to address criticism of Dr. Steinman's credibility and could not have been surprised by the special master's comments about Dr. Steinman's role as an expert witness or his overall experience in the Vaccine Program.

The petitioners note that "the Federal Circuit has held it generally inappropriate to rely on demeanor to discount the testimony of an otherwise qualified expert." (ECF 73 at 7 (citing *Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1266-67 (Fed. Cir. 2011) (O'Malley, J., concurring in part, dissenting in part); *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010)).) Dr. Steinman's demeanor, however, was not the basis for the special master's footnoted comments or his basis for rejecting Dr. Steinman's theory of causation of D.C.'s illness. There is no basis to find that the special master inappropriately relied on Dr. Steinman's demeanor.

The petitioners have not established that the special master abused his discretion in making his credibility determination as to Dr. Steinman or that that credibility determination undermined his ultimate finding rejecting the petitioners' claim.

## B. Support in the Record for the Entitlement Decision

In their third objection, the petitioners challenge the special master's findings regarding T-cell production and the focal aspect of D.C.'s seizures. (ECF 73 at 15-17.) They argue that those findings are contradicted by the evidence and incorrect. (*Id.* at 16-17.) In reviewing the special master's findings of fact, the Court can set aside those findings only if they are found to be arbitrary and capricious. *Turner*, 268 F.3d at 1337; 42 U.S.C. § 300aa-12(e)(2)(B). The Court finds that the special master did provide rational support in the record for his findings.

First, the special master supported his findings regarding Dr. Steinman's explanation of T cells. Dr. Steinman had "opined that the disease process at issue was primarily propagated by cytotoxic T cells . . . ." (ECF 68 at 42.) The special master found that, "as Dr. McCusker observed, a T cell-driven attack on self requires more than just a showing of initial sequential homology." (*Id.* at 43.) The petitioners, instead, had to demonstrate "that the cross-reacting T cells would *recognize* the self structure before concluding they could attack it." (*Id.* (emphasis in original).)

The special master found that that evidentiary showing was not made:

Dr. Steinman's pointing out that some T cells always play a role in antibody production (and hence will be involved even in antibody-driven autoimmune processes) seemed only intended to muddy the waters rather than meet head-on this deficiency in his causation theory, since the kinds of T cells that help the manufacture of antibodies are distinguishable from those that Dr. Steinman posited were causal.

(*Id.*) Although the petitioners take issue specifically with Dr. McCusker's opinion that the flu vaccine would do a poor job of stimulating production of T cells (ECF 73 at 16), Dr. McCusker's opinion concerned the type of T cells at issue. Dr. McCusker, according to the special master, persuasively showed "that the flu vaccine was not even likely to upregulate the type of T cells [Dr. Steinman] deemed central to the relevant disease process." (ECF 68 at 42.) The special master found that Dr. Steinman could not overcome Dr. McCusker's opinion on that point, and that "Dr. Steinman unpersuasively analogized the autoimmune process herein to distinguishable disease processes understood to be *B cell* driven . . . ." (*Id.* (emphasis in original).)

Second, the special master also supported his findings regarding the focal aspect of D.C.'s seizures. The special master found that "Dr. Steinman's opinion ignored Dr. McCusker's point that a peripherally-administered vaccine could not be assumed to 'beeline' for specific locations in the brain, especially since the vaccine's antigens would have other comparably-homologous neuronal targets, in the brain as well as elsewhere in the body." (*Id.*) The petitioners argue that Dr. McCusker provided no support or literature for her contentions, which they allege are scientifically inaccurate. (ECF 73 at 16.) Even Dr. Steinman, however, opined "that the neuronal receptors that [he] deemed homologous with some of the flu vaccine's antigenic components are *not* located solely in the brain." (ECF 68 at 17 (citing ECF 66, Tr. at 176) (emphasis in original).) Dr. Steinman could not provide a scientific basis to reject Dr.

McCusker's contentions; Dr. Steinman testified that medical science could not provide the answer as to why D.C. experienced focal rather than generalized seizures. (ECF 66, Tr. at 176.)

This review of the entitlement decision demonstrates that the special master had a rational factual and scientific basis for reaching his conclusions regarding T-cell production and the focal aspects of D.C.'s seizures. On both topics discussed, Dr. Steinman "ineffectively shield[ed] his theory from challenge" and did not adequately rebut Dr. McCusker's contentions. (See ECF 68 at 43.) The petitioners have not established that the special master's factual findings based on the evidence provided were arbitrary and capricious.

### **C. *Althen* Prongs**

Although in their second objection the petitioners assert that the special master ignored evidence, they do not specify which evidence was ignored. (See ECF 73 at 13-15.) Instead, in that section of their memorandum of objections, they argue that "[t]he [special master] improperly raised Petitioners' burden of proving *Althen* prong one because he required 'more' evidence by insisting Dr. Steinman's testimony, expert reports, and reputable and reliable supporting scientific and medical literature were not enough to support a theory beyond speculation." (*Id.* at 13.) This argument is therefore redundant to the petitioners' fourth objection, in which the petitioners also argue that the special master misapplied the standard of review under *Althen* prong one. In their fifth objection, the petitioners argue that the special master inappropriately reviewed the evidence under *Althen* prong two.

#### **1. Prong One**

Under the first *Althen* prong, the petitioners must "show by preponderant evidence that the vaccination brought about [the] injury by providing . . . a medical theory causally connecting the vaccination and the injury . . ." *Althen*, 418 F.3d at 1278. The petitioners argue that the special master raised their burden for proving the first *Althen* prong by requiring "more" to prove causation. (ECF 73 at 13-15, 17-23.)

The petitioners first argue that the special master's credibility determination of Dr. Steinman affected his analysis of whether the petitioners met their burden of proof. (ECF 73 at 17-19.) Despite the great deference afforded to credibility determinations, "a special master cannot 'cloak the application of an erroneous legal standard in the guise of a credibility determination, and thereby shield it from appellate review.'" *Porter*, 663 F.3d at 1250 (quoting *Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Hum. Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009)). The Federal Circuit has explained that "[w]hat *Andreu* prohibited was for the finder of fact to reject evidence based on an unduly stringent legal test while characterizing the rejection as based on the reliability of particular evidence or the credibility of a particular witness." *Moberly*, 592 F.3d at 1326. Relying on *Porter* and *Andreu*, the petitioners argue that the deferential abuse-of-discretion standard applied to credibility determinations is inappropriate and should not shield the special master's ruling in this case.

Although the special master cannot apply an unduly stringent legal test and characterize it as a credibility determination, "[a]ssessments as to the reliability of expert testimony often turn

on credibility determinations, particularly in cases . . . where there is little supporting evidence for the expert's opinion." *Id.* at 1325-26. The petitioners may prove causation without providing conclusive evidence in medical literature, "[b]ut to say that proof in the form of epidemiological studies or well-established medical experience is not mandatory does not mean that the special masters in Vaccine Act cases are precluded from inquiring into the reliability of testimony from expert witnesses." *Id.* at 1325.

As the special master noted, Dr. Steinman "forthrightly acknowledged that he was unable to offer any literature connecting the flu vaccine to EPC (though he added that recognized medical authorities like the Institute of Medicine . . . had not yet disproven the possibility)." (ECF 68 at 16 (citing ECF 66, Tr. at 240).) In the absence of support in the medical or scientific literature, the special master's assessment of Dr. Steinman's credibility was especially important. *See Moberly*, 592 F.3d at 1325-26.

The special master found that, "[w]hile certain components of [Dr. Steinman's causal] theory *do* have reputable and reliable scientific/medical support, they do not add up to a causation theory that is more than speculative, as many links necessary for the conclusion that the flu vaccine could cause EPC are missing." (ECF 68 at 40 (emphasis in original).) "The core deficiency of Dr. Steinman's opinion," the special master explained, "is the degree to which he relied almost wholly (by his own admission) on sequential homology to carry the day." (*Id.*) In other words, "Dr. Steinman . . . placed far too much emphasis on molecular mimicry and homology in constructing a causation theory" without effectively shielding his theory from challenge. (*Id.* at 43.) As a result, the special master gave less weight to Dr. Steinman's opinions and statements than to Dr. McCusker's. (*Id.*)

In support of their objection to the special master's decision, the petitioners spend much of their argument defending molecular mimicry as a theory of causation, but their argument is misplaced. The special master acknowledged that "molecular mimicry is unquestionably a reliable scientific theory for how autoimmune diseases can pathologically progress." (*Id.* at 41.) He also credited Dr. Steinman's opinion on homology, finding that Dr. Steinman "*was* able to show amino acid homology between the flu vaccine's antigenic components and putative antigenic targets in the brain where an autoimmune form of epilepsy *might* occur . . . ." (*Id.* (emphasis in original).)

The special master explained, however, "that demonstration of homology alone is not enough to establish a preponderant causation theory"—in other words, "more is needed." (*Id.* (emphasis omitted).) "Homology does not inexorably lead to disease"; instead, homology "frequently exists without resulting in autoimmune injury, since the immune system usually is able to prevent an autoimmune cross-reaction, or delete the immune cells that would likely specifically target self structures and proteins." (*Id.*) Dr. McCusker demonstrated "that homology *also* exists between the neuronal receptors Dr. Steinman identified and other wild viruses common in children, but not considered associated with autoimmune forms of epilepsy." (*Id.* (emphasis in original).)

Dr. Steinman, the special master found, was unable to fill the analytical gaps "by citing to his own direct experience, either in researching the adverse effects of the flu vaccine or studying

autoimmune forms of epilepsy.” (*Id.* at 42.) Dr. Steinman’s theory, instead, “borrowed neuronal receptors associated with *other* autoimmune central nervous system injuries to propose how an autoimmune epilepsy would unfold.” (*Id.* (emphasis in original).) As discussed above, Dr. Steinman also could not rebut with medical science “Dr. McCusker’s point that a peripherally-administered vaccine could not be assumed to ‘beeline’ for specific locations in the brain, especially since the vaccine’s antigens would have other comparably-homologous neuronal targets, in the brain as well as elsewhere in the body.” (*Id.*)

The special master’s requiring “more” than a showing of homology is consistent with other cases of this court. For example, in a case affirming a special master’s decision denying entitlement, Judge Horn arrived at a similar conclusion in rejecting Dr. Steinman’s opinion that the flu vaccine at issue in the case had caused rheumatoid arthritis. *Tullio v. Sec’y of Health & Hum. Servs.*, 149 Fed. Cl. 448, 470 (2020). As he does in this case, in *Tullio* Dr. Steinman had relied on molecular mimicry as the basis for his opinion and demonstrated the presence of linear sequence homology. *See id.* at 470-71. His showing of homology, however, was not enough to prove causation: “because all proteins ‘are built from the same 20 amino acids, it is inevitable that some sequences of amino acids will repeat.’” *Id.* at 471 (quoting *Tullio v. Sec’y of Health & Hum. Servs.*, No. 15-51V, 2019 WL 7580149, at \*15 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), *review granted, decision aff’d*, 149 Fed. Cl. 448). The special master in *Tullio* found, and Judge Horn affirmed, “that ‘the finding of sequence homology does not necessarily mean the similarity has significance to the immune system.’” *Id.* (quoting *Tullio*, 2019 WL 7580149, at \*15).<sup>3</sup>

The special master in this case did not require scientific certainty or improperly raise the petitioners’ burden. He reviewed the totality of the evidence and concluded that causation was not shown by a preponderance of evidence. (ECF 68 at 44.) “[T]he *theoretic possibility* of an autoimmune cross-reaction . . . is all demonstrating homology accomplishes—and it does not constitute a preponderant showing.” (*Id.* at 42 (emphasis in original).) Accordingly, the special master concluded “that the preponderant ‘line’ was not crossed” because “Dr. Steinman’s causation theory over-relied on demonstrating sequence homology between components of the flu vaccine and certain neuronal receptors where focal seizures might occur, but without also

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<sup>3</sup> This court recently rejected a special master’s reliance on *Tullio* to find that the petitioner had failed to demonstrate how a flu vaccine had caused arthritis. *See Pankiw v. Sec’y of Health & Hum. Servs.*, No. 15-VV-1082, 2021 WL 3855768, at \*10 (Fed. Cl. Aug. 13, 2021). In that case, Judge Roumel could not “determine on the record before [her] whether the Special Master accurately addressed Petitioner’s particular circumstances” because the special master “heavily relie[d] on his previous decision in *Tullio*, without addressing the specific facts of Petitioner’s case.” *Id.* In *Pankiw*, the special master failed to acknowledge that the petitioner’s treating physician had attributed the petitioner’s diagnosis to the petitioner’s vaccine. *Id.* Here, however, the petitioners have neither alleged nor demonstrated that the special master failed to address D.C.’s particular circumstances. The special master also did not fail to acknowledge testimony of treater witnesses on causation; the petitioners’ treater witnesses declined to testify about causation.

proposing additional reliable evidence necessary to find that the flu vaccine could be associated with autoimmune epilepsy/EPC.” (*Id.* at 44.)

The petitioners have not demonstrated that the special master improperly raised their burden under *Althen* prong one.

## **2. Prong Two**

Failing the first *Althen* prong was fatal to the petitioners’ claim, but the special master nevertheless analyzed the second prong, finding that the petitioners also did not meet that prong. (ECF 68 at 44-45.) Under the second *Althen* prong, the petitioners must provide “a logical sequence of cause and effect showing that the vaccination was the reason for the injury . . . .” *Althen*, 418 F.3d at 1278. This showing “must be supported by a sound and reliable medical or scientific explanation.” *Knudsen by Knudsen v. Sec’y of Dep’t of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). The petitioners argue that the special master raised their burden for proving the second *Althen* prong by requiring scientific evidence that does not exist. (ECF 73 at 23-26.)

The petitioners argue that the special master improperly required both evidence that D.C.’s treating physicians connected the flu vaccine with her condition and a test to demonstrate an exact biologic mechanism. The special master required neither; he mentioned the absence of that evidence while surveying the available evidence in the record. He noted that “treater support for the vaccine being causal is sparse, with no actual treaters opining ‘in real time’ that the vaccine could have caused seizures that ultimately manifested months after vaccination.” (ECF 68 at 45.) He also noted that “D.C. never tested positive for any autoantibodies that would be associated with an autoimmune form of epilepsy—and while this fact may not have prevented treaters from confirming their ultimate diagnosis, it somewhat undercuts the conclusion that the flu vaccine caused it . . . .” (*Id.* at 44-45.)

Those factors, however, were not dispositive. The special master considered the totality of the evidence before him. The “larger issue” than those on which the petitioners base their objection was “the course of [D.C.’s] illness from vaccination to manifestation of acute seizures.” (*Id.* at 45.) The special master accepted the petitioners’ evidence showing that “D.C. likely experienced a febrile seizure associated with her receipt of the flu vaccine that same day, despite the testimony of Respondent’s experts that this diagnosis lacked some evidentiary support.” (*Id.* at 44.) This conclusion did not lead to a finding that the second prong of *Althen* had been satisfied “because Dr. Steinman disavowed the febrile seizure as having any relationship to D.C.’s later-diagnosed EPC,” and, as a result, “the vaccine’s causal relationship to a one-time febrile seizure ha[d] no bearing on entitlement in this case.” (*Id.*)

In arguing that the special master improperly required scientific evidence that does not exist, the petitioners have mischaracterized the evidence, linking D.C.’s initial febrile seizure to her EPC:

Dr. Steinman’s reports provide a persuasive medical explanation of a logical sequence of cause and effect between the flu vaccine DC



received on January 22, 2014 and DC's neurological injuries which, *although developed that night as febrile seizures, eventually progressed over the subsequent weeks to more apparent seizure activity due to damage to DC's brain tissue through the process of autoimmunity*, leading to an autoimmune disorder (i.e., autoimmune mediated epilepsy).

(ECF 73 at 24 (emphasis added).) In contradiction to the petitioners' proffered sequence, Dr. Steinman testified that he was "not necessarily drawing a bridge between the febrile seizure initially and what happened a few weeks later with the eye twitching, which [he] think[s] was the undisputed beginning of the EPC and of the autoimmune condition." (ECF 66, Tr. at 211.)

The special master concluded from Dr. Steinman's testimony that "Dr. Steinman did *not* connect D.C.'s febrile seizure *at all* to her subsequent disorder," and, even if the vaccine had caused her febrile seizure, "Dr. Steinman *did not contend* that this seizure was the onset of her alleged vaccine-caused injury." (ECF 68 at 15 (citing ECF 67, Tr. at 266-67) (emphasis in original).) The special master found that Dr. Steinman "was unsuccessful in explaining how a flu vaccine might initiate a neurologic process that would take several months before becoming acute" and "did not establish that the T cells he maintains would be increased due to an autoimmune cross-reaction instigated by molecular mimicry would first cause eye twitching that would later change into focal seizures." (*Id.* at 45.)

Ultimately, after reviewing all the evidence together, the special master found that the petitioners could "only point to the fact that vaccination occurred first," which does not prove causation. (ECF 68 at 45 (citing *Moberly*, 592 F.3d at 1323 (holding that a temporal association alone does not prove causation)).)

The petitioners have not shown that the special master raised their burden under the second prong of *Althen*.

#### **IV. CONCLUSION**

The Court must apply the deferential standard applicable to motions for review under the Vaccine Program. Despite the footnoted criticisms of Dr. Steinman in the entitlement decision, the special master accepted many of Dr. Steinman's opinions. The special master, however, found Dr. Steinman's theory inadequate to establish causation and, in so finding, provided a thorough analysis for rejecting the claim. The entitlement decision is supported by the record.

The Court finds that the special master acted in accordance with the law and did not abuse his discretion or act arbitrarily and capriciously.

The petitioners' motion for review (ECF 71) is **DENIED**. The special master's entitlement decision denying compensation to the petitioners (ECF 68) is **AFFIRMED**.

The Clerk is **DIRECTED** to enter judgment accordingly.

The parties shall review this decision and notify the Court no later than **December 17, 2021**, of any proposed redactions to the opinion so that the Court may publicly issue the opinion.

s/ Richard A. Hertling

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**Richard A. Hertling**

**Judge**